MINUTES OF THE April 13th, 2010 PHARMACY AND THERAPEUTICS (P & T) COMMITTEE MEETING

MEMBERS ATTENDING: Hosan Azomani, MD; Joyce Brewer PhD; Sharon Dickey, PharmD; Ryan Harper, PharmD; Lonnie Hicks R.Ph.; Deborah Minor, PharmD; William Sorey, MD; Carol Tingle, MD; Lee Voulters MD; Pearl Wales, PharmD

Also present: Judith Clark, RPh, Pharmacy Director, DOM; Paige Clayton, PharmD, DOM; Terri Kirby, RPh, DOM; J. David Wuest RPh Provider Synergies; Steve Liles, PharmD, Provider Synergies

MEMBERS ABSENT: Larry Calvert, RPh; Michael O'Dell, MD

CALL TO ORDER: Dr. Minor called the meeting to order.

INTRODUCTIONS: Ms. Clark welcomed attendees to the meeting and asked everyone at the table to introduce themselves. She thanked the Committee members for their work and introduced the DOM pharmacy staff and attendees from DOM's other pharmacy vendors, HID and ACS. ACS participated in the meeting via tele-conference.

ADMINISTRATIVE MATTERS: Ms. Clark outlined procedural and safety guidelines for the meeting. She noted that the P&T Committee is an advisory Committee and that the DOM has the final say regarding the PDL. She stated that the PDL decisions for classes reviewed at this meeting would be effective on July 1, 2010 and that minutes from this meeting would be posted no later than May 13th, 2009. She also stated that the State of Mississippi Medicaid Program is in a serious financial situation, like many States the need for assistance is higher than available funds. Ms. Clark recognized that this would be the last meeting for Dr. Wales and thanked her for her service.

DRUG CLASS ANNOUNCEMENTS: Ms. Clark stated that DOM and Provider Synergies continually review drug classes for the PDL process based on the clinical and financial benefits of so doing. The Bile Salt class will be reviewed at the next meeting. It was placed on the proposed agenda with the expectation that a new product would be entering the class. The product did not make it to market in time to be presented. She also stated that the Cough and Cold products would be reviewed at the next meeting because a change in CMS's coverage policy has cause a recent reorganization of the class.

APPROVAL OF MARCH 9TH, 2010 MEETING MINUTES: Dr. Minor asked for changes or a motion to approve the minutes from the April 9th, 2010 P&T Committee meeting. Mr. Wuest stated that the draft minutes failed to show that motion and the Board's approval of the motion for the Lipotropics, Statins Class included Crestor as a preferred agent. Dr. Dickey requested her profession designation be corrected to PharmD. Dr. Voulters requested the proper spelling of his name. Dr. Azomani moved to approve the minutes with these changes. Dr. Wales seconded the motion and the minutes were approved unanimously.

THERAPEUTIC CLASS REVIEWS: Mr. Wuest stated that he would be presenting new information not previously covered in the Committee's reviews.

BONE RESORPTION SUPPRESSION AND RELATED AGENTS

Mr. Wuest presented a brief overview noted that this class has two new agents in it since the last time the Committee reviewed it. His overview included a summary of the North American Menopause Society's 2010 position statement.

Mr. Wuest presented the PDL recommendations for the class:

Brand Name	Current PDL Status	PDL Recommendation
ACTONEL (ORAL)	PDL	PDL
ACTONEL W/CALCIUM (ORAL)	PDL	PDL
ALENDRONATE TABLETS (ORAL)	PDL	PDL
BONIVA (ORAL)	NPD	NPD
CALCITONIN SALMON (NASAL)	PDL	PDL
DIDRONEL (ORAL)	NR	NPD
ETIDRONATE DISODIUM (ORAL)	NR	NPD
EVISTA (ORAL)	PDL	NPD
FORTEO (SUBCUTANE.)	NPD	NPD
FORTICAL (NASAL)	PDL	PDL
FOSAMAX PLUS D (ORAL)	PDL	PDL
FOSAMAX SOLUTION (ORAL)	PDL	PDL
MIACALCIN (NASAL)	PDL	PDL

No public testimony on this class was provided. Jack Putman MD, Merck, yield back his time for Fosamax-D.

<u>Dr. Azomani made a motion to accept Provider Synergies' recommendations as presented.</u> The motion was seconded by Dr. Harper. The motion passed unanimously.

GROWTH HORMONE

Mr. Wuest noted that this class has no new agents in it since the last time the Committee reviewed it. He provided an overview of the class.

Mr. Wuest presented multiple PDL recommendations for the class. The Committee decided to utilize the following:

Brand Name	Current PDL Status	PDL Recommendation
GENOTROPIN (INJECTION)	PDL	NPD
HUMATROPE (INJECTION)	NPD	NPD
NORDITROPIN (INJECTION)	NPD	NPD
NUTROPIN (INJECTION)	PDL	PDL
NUTROPIN AQ (INJECTION)	PDL	PDL
OMNITROPE (INJECTION)	NPD	NPD
SAIZEN (INJECTION)	PDL	NPD
SAIZEN (INJECTION)	PDL	NPD
SEROSTIM (INJECTION)	NPD	NPD
TEV-TROPIN (INJECTION)	NPD	NPD
ZORBTIVE (INJECTION)	NPD	NPD

Public testimony on this class was provided on Norditropin by Dr. Fran Gander on behalf of Novo Nordisk, on Nutropin by George Moll MD on behalf of Genetech, and on Genotropin by Lee Ann Griffin PharmD on behalf of Pfizer.

<u>Dr. Brewer made a motion to accept Provider Synergies' recommendations as presented.</u> The motion was seconded by Dr. Azomani. The motion passed with a 9-1 vote with Dr Wales voting nay.

HYPOGLYCEMICS, MEGLITINIDES

Mr. Wuest presented a brief overview of the class including the ADA consensus algorithm.

Mr. Wuest presented the following PDL recommendations for the class:

Brand Name	Current PDL Status	PDL Recommendation
NATEGLINIDE (ORAL)	PDL	PDL
PRANDIMET (ORAL)	NPD	NPD
PRANDIN (ORAL)	PDL	PDL
STARLIX (ORAL)	PDL	PDL

No public testimony on this class was provided.

<u>Dr. Voulters made a motion to accept the recommendations as presented.</u> Dr. Harper seconded the motion, which passed unanimously.

HYPOGLYCEMICS, TZDs

Mr. Wuest noted that this class has no new agents in it since the last time the Committee reviewed it. He provided a brief overview of the class including the advisory release in February 2010 by the AHA and the ACCF.

Mr. Wuest presented the PDL recommendations for the class:

Brand Name	Current PDL Status	PDL Recommendation
ACTOPLUS MET (ORAL)	PDL	PDL
ACTOS (ORAL)	PDL	PDL
AVANDAMET (ORAL)	PDL	PDL
AVANDARYL (ORAL)	PDL	PDL
AVANDIA (ORAL)	PDL	PDL
DUETACT (ORAL)	PDL	PDL

No public testimony on this class was provided. Ray Massengill PharmD, GSK yielded back his time for Avandia/Avandamet.

<u>Dr. Dickey made a motion to accept Provider Synergies' recommendations as presented.</u> The motion was seconded by Dr. Sorey. The motion passed unanimously.

HYPOGLYCEMICS, INCRETIN MIMETICS/ENHANCERS

Mr. Wuest presented a brief overview of the class. He stated that the class has no new agents since the last review. This was corrected by Dr. Steve O'Brien. Dr O'Brien stated that Victoza had entered the market at the beginning of 2010. Dr. O'Brien provided the committee with a detailed overview of Victoza.

Mr. Wuest then presented the PDL recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
BYETTA PENS (SUBCUTANE.)	PDL	PDL
JANUMET (ORAL)	PDL	PDL
JANUVIA (ORAL)	PDL	PDL
ONGLYZA (ORAL)	PDL	PDL
SYMLIN (SUBCUTANE.)	NPD	NPD
SYMLIN PENS (SUBCUTANE.)	NPD	NPD
VICTOZA (SUBCUTANE.)	NPD	NPD

Public testimony on this class was provided on Symlin by Milton Kleinpeter on behalf of Amylin, on Victoza by Dr. Steve O'Brien on behalf of Nova Nordisk.

Milton Kleinpeter from Amylin, Jack Putman M.D. from Merck, and Dr. Kris Washington from Bristol-Myers Squibb yielded their time back to the Committee.

<u>Dr. Wales made a motion to approve the recommendations as presented by Provider Synergies</u>. The motion was seconded by Dr. Brewer and passed unanimously.

HYPOGLYCEMICS, INSULIN AND RELATED AGENTS

Mr. Wuest presented a brief overview of the class.

Mr. Wuest presented the PDL recommendations for this class:

Brand Name	Current PDL Status	PDL Recommendation
APIDRA (SUBCUTANE.)	NPD	NPD
APIDRA PENS (SUBCUTANE.)	NPD	NPD
HUMALOG (SUBCUTANE.)	NPD	NPD
HUMALOG MIX (SUBCUTANE.)	NPD	NPD
HUMALOG MIX PENS (SUBCUTANE.)	NPD	NPD
HUMALOG PENS (SUBCUTANE.)	NPD	NPD
HUMULIN (SUBCUTANE.)	NPD	NPD
HUMULIN PENS (SUBCUTANE.)	NPD	NPD
LANTUS (SUBCUTANE.)	PDL	PDL
LANTUS PENS (SUBCUTANE.)	PDL	PDL
LEVEMIR (SUBCUTANE.)	PDL	PDL
LEVEMIR PENS (SUBCUTANE.)	PDL	PDL
NOVOLIN (SUBCUTANE.)	PDL	PDL
NOVOLIN PENS (SUBCUTANE.)	PDL	PDL
NOVOLOG (SUBCUTANE.)	PDL	PDL
NOVOLOG MIX 70/30 (SUBCUTANE.)	PDL	PDL
NOVOLOG MIX 70/30 PENS (SUBCUTANE.)	PDL	PDL
NOVOLOG PENS (SUBCUTANE.)	PDL	PDL

Public testimony on this class was provided on Humulin/Humalog by Kirsten Mar PharmD on behalf of Eli Lilly, on Lantus/Apidra by Deborah Epps PharmD on behalf of Sanofi-Avantis.

Dr Steve O'Brien from Novo Nordisk and Leigh Ann Griffin PharmD from Pfizer yielded their time back to the Committee.

<u>Dr. Voulters made the motion to approve the recommendations as presented by Provider Synergies.</u> The motion was seconded by Dr. Wales and approved unanimously by the Committee.

PROTON PUMP INHIBITORS

Mr. Wuest noted that this class has no new agents in it since the last time the Committee reviewed it. Kapidex experienced a name change to Dexilant. He provided an overview of the class.

Mr. Wuest presented the PDL recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ACIPHEX (ORAL)	NPD	NPD
KAPIDEX (ORAL)	PDL	PDL
LANSOPRAZOLE (ORAL)	PDL	NPD
NEXIUM (ORAL)	NPD	NPD
NEXIUM SUSPENSION (ORAL)	NPD	NPD
OMEPRAZOLE (ORAL)	PDL	PDL
OMEPRAZOLE OTC (ORAL)	PDL	NPD
PANTOPRAZOLE (ORAL)	NPD	NPD
PREVACID (ORAL)	PDL	NPD
PREVACID OTC (ORAL)	NPD	NPD
PREVACID SOLUTAB (ORAL)	PDL	PDL
PRILOSEC OTC (ORAL)	NPD	NPD
PRILOSEC SUSPENSION (ORAL)	NPD	NPD
PROTONIX SUSPENSION (ORAL)	NPD	NPD

No public testimony on this class was provided.

<u>Dr. Azomani made a motion to accept the recommendations as presented.</u> This motion was seconded by Dr. Brewer. The motion passed unanimously.

ANTIEMETICS

Mr. Wuest presented an overview of the class which included the 2009 National Comprehensive Cancer Network guidelines for treatment.

Mr. Wuest presented the PDL recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ANZEMET (ORAL)	NPD	NPD
CESAMET (ORAL)	NPD	NPD
DRONABINOL (ORAL)	NPD	NPD
EMEND (ORAL)	NPD	NPD
GRANISETRON (ORAL)	NPD	NPD
ONDANSETRON / ODT (ORAL)	PDL	PDL
SANCUSO (TRANSDERMAL)	NPD	NPD

Public testimony on this class was provided on Emend by Jack Putman MD on behalf of Merck.

<u>Dr. Voulters made a motion to accept the recommendations as presented.</u> The motion was seconded by Dr. Brewer and passed unanimously.

ULCERATIVE COLITIS AGENTS

Mr. Wuest presented overview of this therapeutic class including information regarding sfRowasa a new sulfite-free mesalamine enema formulation and Asacol HD a new delayed release mesalamine tablet formulation.

Mr. Wuest made the following recommendations to the Committee:

Brand Name		PDL Recommendation
APRISO (ORAL)	NPD	PDL
ASACOL (ORAL)	PDL	PDL
BALSALAZIDE (ORAL)	PDL	PDL
CANASA (RECTAL)	PDL	PDL
DIPENTUM (ORAL)	PDL	PDL
LIALDA (ORAL)	PDL	NPD
MESALAMINE (RECTAL)	PDL	PDL
PENTASA (ORAL)	PDL	PDL
sfROWASA (RECTAL)	NPD	NPD
SULFASALAZINE (ORAL)	PDL	PDL

Public testimony on this class was provided on Lialda by Carey Hall PharmD on behalf of Shire. Time for Pentasa was yielded back.

<u>Dr. Brewer made a motion to accept the recommendations as presented.</u> The motion was seconded by Dr. Harper and passed unanimously.

ANTIBIOTICS GI

Mr. Wuest stated that Flagyl ER is now FDA approved for the treatment of Bacterial Vaginosis (BV). Currently the CDC does not include Flagyl ER in the preferred recommended treatments in the management of BV.

He presented the following PDL recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ALINIA (ORAL)	PDL	PDL
FLAGYL ER (ORAL)	NPD	NPD
METRONIDAZOLE (ORAL)	PDL	PDL
NEOMYCIN (ORAL)	PDL	PDL
TINDAMAX (ORAL)	PDL	PDL
VANCOCIN HCL (ORAL)	NPD	NPD
XIFAXAN (ORAL)	NPD	NPD

No public testimony on this class was provided.

<u>Dr. Sorey made a motion to accept the recommendations as presented.</u> The motion was seconded by Dr. Azomani and passed unanimously by the Committee.

ANTIHISTAMINES, MINIMALLY SEDATING

Mr. Wuest presented an overview of the class including a new study comparing desloratedine versus levocetirizine. There were no new agents in this class since the last time the Committee review the class. Dr Voulters requested that Provider Synergies split the decongestive containing product from their single agent counterparts.

Mr. Wuest made the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ALLEGRA ODT (ORAL)	NPD	NPD
ALLEGRA SYRUP (ORAL)	NPD	NPD
ALLEGRA-D 12-HOUR (ORAL)	NPD	NPD
ALLEGRA-D 24-HOUR (ORAL)	NPD	NPD
CETIRIZINE / CETIRIZINE-D (ORAL)	PDL	PDL
CETIRIZINE SYRUP (ORAL)	PDL	PDL
CETIRIZINE SYRUP RX (ORAL)	PDL	PDL
CLARINEX / CLARINEX-D (ORAL)	NPD	NPD
CLARINEX SYRUP (ORAL)	NPD	NPD
CLARITIN CHEW OTC (ORAL)	NPD	NPD
FEXOFENADINE (ORAL)	NPD	NPD
FEXOFENADINE-D 12-HOUR (ORAL)	NPD	NPD
LORATADINE / LORATADINE-D (ORAL)	PDL	PDL
LORATADINE SYRUP (ORAL)	PDL	PDL
SEMPREX-D (ORAL)	PDL	PDL
XYZAL (ORAL)	NPD	PDL
XYZAL SYRUP (ORAL)	NPD	PDL

Public testimony on this class was provided on Clarinex by Jack Putman MD on behalf of Merck.

<u>Dr. Azomani made a motion to accept the recommendations as presented.</u> The motion was seconded by Dr. Wales and passed unanimously by the Committee.

PANCREATIC ENZYMES

Mr. Wuest noted that Zenpep has been added to this class since the last time the Committee reviewed it. He provided an overview of the class including recent developments regarding the FDA policy to make all products in this submit drug applications.

Mr. Wuest presented multiple PDL recommendations for the class. The Committee decided to utilize the following recommendation:

Brand Name	Current PDL Status	PDL Recommendation
CREON (ORAL)	PDL	PDL
PANCREASE MT (ORAL)	PDL	NPD
PANCRECARB MS (ORAL)	NPD	NPD
PANCRELIPASE (ORAL)	PDL	PDL
ULTRASE (ORAL)	PDL	NPD
VIOKASE (ORAL)	PDL	PDL
ZENPEP (ORAL)	NPD	PDL

Public testimony on this class was provided on Creon by Pam Sardo PharmD on behalf of Abbott. Melissa Fezer from Eurand yielded her time back.

<u>Dr. Brewer made a motion to approve the PDL as recommended.</u> The motion was seconded by Dr. Harper and was passed unanimously.

INTRANASAL RHINITIS AGENTS

Mr. Wuest presented clinical data on agents in this class.

Mr. Wuest presented multiple PDL recommendations for the class. The Committee decided to utilize the following recommendation:

Brand Name	Current PDL Status	PDL Recommendation
ASTELIN (NASAL)	PDL	NPD
ASTEPRO (NASAL)	PDL	PDL
BECONASE AQ (NASAL)	NPD	NPD
FLONASE (NASAL)	PDL	NPD
FLUNISOLIDE (NASAL)	PDL	PDL
FLUTICASONE (NASAL)	PDL	NPD
IPRATROPIUM (NASAL)	PDL	PDL
NASACORT AQ (NASAL)	NPD	NPD
NASONEX (NASAL)	PDL	PDL
OMNARIS (NASAL)	NPD	NPD
PATANASE (NASAL)	PDL	PDL
RHINOCORT AQUA (NASAL)	NPD	NPD
VERAMYST (NASAL)	PDL	PDL

Todd Adkins MD from GSK and Jack Putman MD from Merck yielded their time back to the Committee.

<u>Dr. Voulters made a motion to accept the recommendations as presented.</u> Dr. Azomani seconded the motion, which then passed unanimously.

LEUKOTRIENE MODIFIERS

Mr. Wuest presented an overview of this class which included a new study supporting current data that montelukast improves lung function in children with allergic rhinitis and asthma.

He then presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ACCOLATE (ORAL)	PDL	PDL
SINGULAIR (ORAL)	PDL	PDL
ZYFLO CR (ORAL)	NPD	NPD

No public testimony on this class was provided. Jack Putman MD, Merck yield back his time.

<u>Dr. Dickey made a motion to accept the recommendations as presented.</u> Dr. Wales seconded the motion, which then passed unanimously.

ANDROGENIC AGENTS

Mr. Wuest stated that there is no significant new clinical information to present for this class, but he did provide an overview of the class.

Mr. Wuest presented the PDL recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ANDRODERM (TRANSDERM.)	PDL	PDL
ANDROGEL (TRANSDERM.)	PDL	PDL
TESTIM (TRANSDERM.)	NPD	NPD

Pam Sardo PharmD from Abbott yielded her time back to the Committee.

<u>Dr. Wales made a motion to approve the recommendations.</u> The motion was seconded by Dr. Dickey. The motion was approved unanimously.

BRONCHODILATORS, BETA AGONIST

Mr. Wuest states that there were no new agents in this class he did provide an overview of the class.

Mr. Wuest presented multiple PDL recommendations for the class. The Committee decided to utilize the following recommendation:

Brand Name	Current PDL Status	PDL Recommendation
ALBUTEROL (ORAL)	PDL	PDL
ALBUTEROL NEBULIZER (INHALATION)	PDL	PDL
ALBUTEROL NEBULIZER LOW-DOSE (INHALATION)	PDL	PDL
BROVANA (INHALATION)	NPD	NPD
FORADIL (INHALATION)	PDL	PDL
LEVALBUTEROL (INHALATION)	NPD	NPD
MAXAIR (INHALATION)	NPD	NPD
METAPROTERENOL (ORAL)	PDL	PDL
PERFOROMIST (INHALATION)	NPD	NPD
PROAIR HFA INHALER (INHALATION)	PDL	NPD
PROVENTIL HFA (INHALATION)	PDL	NPD
SEREVENT (INHALATION)	NPD	NPD
TERBUTALINE (ORAL)	PDL	PDL
VENTOLIN HFA (INHALATION)	PDL	PDL
XOPENEX (INHALATION)	NPD	NPD
XOPENEX HFA (INHALATION)	NPD	NPD

Public testimony on this class was provided on Ventolin HFA by Todd Adkins MD on behalf of GSK, and on Proventil HFA/Foradil by Jack Putman MD on behalf of Merck.

Patrick Harvey R.Ph. from Sepracor yielded his time back.

Dr. Azomani made a motion to accept the recommendations as presented with Proair HFA as preferred. Dr Voulters requested that Dr Azomani amend his recommendation to make Proair HFA non-preferred, Dr Azomani accepted the amendment. The motion was seconded by Dr. Tingle and passed unanimously.

BRONCHODILATORS, ANTICHOLINERGIC

Mr. Wuest provided an overview of the class including an analysis of the UPLIFT trial and the FDA review and recommendation of continued use of an agent in the class completed in January of 2010.

Mr. Wuest presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ATROVENT HFA (INHALATION)	PDL	PDL
COMBIVENT (INHALATION)	PDL	PDL
IPRATROPIUM / ALBUTEROL (INHALATION)	NPD	NPD
IPRATROPIUM NEBULIZER (INHALATION)	PDL	PDL
SPIRIVA (INHALATION)	PDL	PDL

No public testimony on this class was provided.

<u>Dr. Sorey made a motion to accept the recommendations as presented.</u> The motion was seconded by Dr. Harper and passed unanimously

GLUCOCORTICOIDS, INHALED

Mr. Wuest provided an overview of the class including Azmacort's removal from the market and four new relevant clinical trials.

Mr. Wuest presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ADVAIR / ADVAIR HFA (INHALATION)	PDL	PDL
AEROBID/AEROBID-M (INHALATION)	PDL	PDL
ALVESCO (INHALATION)	NPD	NPD
ASMANEX (INHALATION)	PDL	PDL
BUDESONIDE RESPULES (INHALATION)	PDL	PDL
FLOVENT/FLOVENT HFA (INHALATION)	PDL	PDL
PULMICORT FLEXHALER (INHALATION)	NPD	PDL
PULMICORT RESPULES (INHALATION)	PDL	PDL
QVAR (INHALATION)	PDL	PDL
SYMBICORT (INHALATION)	PDL	PDL

Benjamin Everett from AstraZeneca, Todd Adkins MD from GSK, Patrick Harvey R.Ph. from Sepracor, and Jack Putman from Merck yielded their time back to the Committee.

<u>Dr. Azomani made a motion to accept the recommendations as presented.</u> The motion was seconded by Dr. Tingle and passed unanimously.

OTHER BUSINESS

There was no other business.

NEXT MEETING DATE

Ms. Clark stated that the next P&T Committee meeting is tentatively scheduled to be October 12th 2010.

ADJOURNMENT

There being no further business, Dr. Minor adjourned the meeting.